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TERUMO MEDICAL CORPORATION

REGULATORY AFFAIRS DEPARTMENT
125 BLUE BALL ROAD
ELKTON, MARYLAND 21921
TELEPHONE: (410) 392-7231
FAX: (410) 398-6079

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

February 22, 2000

RE: Docket No. 99N-4784
Premarket Notification; Requirement for Redacted Version of Substantially Equivalent Premarket Notification

To Whom It May Concern:

Please enter the following comments to the above docket:

1. Requiring all 510k's to be redacted in anticipation of an FOIA request is burdensome and unnecessary for the manufacturer because a specific 510k may never be requested. FDA's estimation of 2 hours for redaction of 510k's is underestimated. How did FDA arrive at 2 hours.

2. When we receive 510k's which have been redacted they contain letters, memos and comments from FDA reviewers. This proposed rule does not address how we can assure the information in those letters, memos, and comments (that are not part of the original 510k submission) can be redacted. Our experience is that some of the communications, memos, etc do contain confidential information. It is important that the FDA reviewers' communications be part of the document received from FOIA. This is how we can understand FDA's concerns about types of devices. This is one of the reasons we request 510k's through FOIA. However, it is also imperative that the sponsor have the opportunity to redact this information also. How does this proposed rule intend to address this issue?

3. FDA only states that a "significant volume" of FOIA requests are processed. Of the total number of cleared 510k's, what percentage (25%, 50%, 75%) of 510k's are requested relative to the number of 510k's cleared? Is this unnecessarily burdensome for the manufacturer?

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4. One 510k requirement is the submission of the substantially equivalent device labeling and instructions for use (IFU). Many companies copyright their IFU. FDA's proposed rule prohibits inclusion of any copyrighted material unless the applicant also submits written consent from the holder of the copyright. This will have a significant negative impact on the sponsor. How can the applicant proceed if the competitor refuses consent? Additionally, the request for consent from the competitor notifies the competitor that your company is submitting a 510k for a specific type of device. The existence of a 510k submission should be held confidential until clearance. How does FDA expect sponsors to handle this situation?

3. The number of 510k submissions is a significant volume (3668 cleared in 1998) and the number may continue to increase. How has FDA prepared to manage, store, archive and retrieve the large volume of redacted files? Keeping in mind that a large number of these 510k's may never be requested through FOIA, has FDA created an unnecessary burden for themselves?

4. Terumo disagrees with automatically placing the redacted files on the FDA website. The information becomes too readily disseminated and may be abused.

5. There will be manufacturers who don't comply with providing redacted 510k submissions. What action will FDA take to enforce this requirement? Will FDA revoke the 510k if the redacted version is not received within 30 days? What mechanism does FDA have to follow up and assure all redactions are received within 30 days?

6. We agree that some system enhancement is necessary for obtaining documents through FOIA. We have waited up to three years to receive some information requested. We still have outstanding requests for over 18 months.

We look forward to FDA review and discussion of the above comments.

With Best Regards,

Sandi Hartka

Sandi Hartka
Manager Regulatory Affairs

REF: SH00-180

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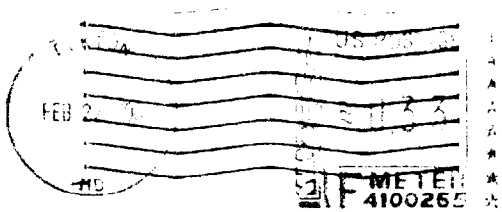

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